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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,098	05/02/2001	David Grant Richards		3884

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/647,098		
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

--The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

THE REPLY FILED 08 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *08 October 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): 112, first paragraph.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *none*.

   Claim(s) objected to: *none*.

   Claim(s) rejected: *11-15*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See Advisory Attachment.*

Advisory Action Attachm nt

1. Applicants amendment filed October 8, 2003 is acknowledged. Claims 1-10 have been cancelled. Claims 11-15 have been added.

Rejection Withdrawn

2. In view of Applicant's amendment the rejection under 35 U.S.C. 112, first paragraph, pages 2-3, paragraph 3 is withdrawn.

Rejections Maintained

3. The rejection under 35 U.S.C. 102/103 anticipated by or obvious over MacDonald et al is maintained for newly submitted claims 11-15 the reasons set forth on pages 6-7 paragraph 5 of the previous Office Action.

The rejection was on the grounds that McDonald et al teach vaccines against coccidiosis in domestic fowls that contain attenuated precocious strains of *Eimeria* species (see the Abstract). McDonald et al teach a vaccine that contains *E. aceruvlina*, *E. maxima*, *E. tenella*, *E. necatrix*, *E. mitis*, *E. brunetti* and *E. praecox* (claim 1, column 14). McDonald et al teach that the vaccines of their invention include chicken feed or drinking water containing the attenuated *Eimeria* strains (column 6).

McDonald et al do not specifically teach one or more strains of *E. maxima* ARI-73/97, *E. acerculina* ARI-77/97, *E. tenella* ARI-11/98, E. necatrix MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said strains. However, in the alternative the strains of McDonald, et al appear to be obvious or analogous variants of the claimed vaccine strains. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the bacteria strains of McDonald et al in a vaccine against coccidiosis because McDonald teach vaccines active against coccidiosis in domestic fowls that contain attenuated precocious strains of *Eimeria* species. It would have been expected, barring evidence to the contrary, that vaccines comprising multiple *Eimeria* species as taught by McDonald et al would be effective in the prevention and control of coccidiosis in poultry.

Applicant urges that they have submitted new claims and the rejection under MacDonald is moot. Applicant urges that MacDonald et al do not teach or suggest the subject matter of the newly submitted claims. Applicant urges the *Eimeria* strains of MacDonald et al are distinct from that of the claimed *Eimeria* strains. Applicant urges that the organisms of MacDonald et al provide immunity only after 31 days of heterologous or homologous challenge and Applicant urges that this is in contrast to the claimed *Eimeria* strains which realized a 21 day protective immune response. Applicant urges that the organisms of MacDonald et al have a prepatent time in the range 60-125 hours and the claimed organisms have a sporulation time of between 18 and 30 hours. Applicant urges the claimed vaccines comprising strains isolated from Australia are unique and are not disclosed or suggested by the prior art.

Applicant's arguments filed October 8, 2003 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing of the record to show why the vaccine of the prior art teachings is not the same as the claimed invention. The claims are drawn to a vaccine comprising *Eimeria maxima*, *E. acervulina, E. tenella* and optionally at least one *E. necatrix*. MacDonald et al teach vaccines against coccidiosis in domestic fowls that contain attenuated precocious strains of *Eimeria* species which include *E. aceruvlina, E. maxima, E. tenella, E. necatrix, E. mitis, E. brunetti and E. praecox*. Applicant is urging process limitations in a product claim with their assertion that "the organisms of MacDonald et al have a prepatent time in the range 60-125 hours which is in contrast to the claimed organisms that have a sporulation time of between 18 and 30 hours". It should be remembered

that products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 29222-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Applicant is arguing limitations of intended use with their assertion that "that the organisms of MacDonald et al provide immunity only after 31 days of heterologous or homologous challenge which is in contrast to the claimed *Eimeria* strains which realized a 21 day protective immune response". It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is

capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). It should also be remembered that the claims are drawn to a product, a vaccine. MacDonald et al teach a vaccine that comprises the same *Eimeria* species as the claimed vaccine. Applicant has provided no side-by-side comparison to show that the claimed vaccine differs from the vaccine of the prior art. Therefore, the vaccine of the prior art anticipates or makes obvious the claimed invention.

4. The rejection under 35 U.S.C. 102/103 anticipated by or obvious over Shirley is maintained for newly submitted claims 11-15 the reasons set forth on pages 7-9 paragraph 6 of the previous Office Action.

The rejection was on the grounds that Shirley teaches a vaccine composition which comprises live attenuated strains of *Eimeria* species in particular *E. necatrix* and *E. acervulina*. Shirley teaches that the *Eimeria* species may be in the form of sporocysts and that other *Eimeria* species such as *E. maxima*, *E. brunetti, E. mivati, E. tenella* and *E. praecox* may be added to provide a fully effective coccidiosis vaccine (column 4, lines 35-41). Shirley teaches that other vaccines comprising antigenic material from other species of organisms besides *Eimeria* may be used in the invention (column 4, lines 54-56). Shirley teaches that the vaccines are formulated using a sterile aqueous medium which may contain suspension agents such as gelatin (column 4, lines 60-63).

Shirley does not specifically teach one or more strains of *E. maxima* ARI-73/97, *E. acerculina* ARI-77/97, *E. tenella* ARI-11/98, E. necatrix MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said strains. However, in the alternative, the strains of Shirley appear to be obvious or analogous variants of the claimed vaccine strains. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the bacteria strains of Shirley in a vaccine against coccidiosis because Shirley teaches that live vaccines comprising attenuated strains of *Eimeria* species may be formulated in the feed or drinking water of animals and these vaccines are used to

prevent and control coccidiosis in poultry. It would have been expected, barring evidence to the contrary, that vaccines comprising multiple *Eimeria* species as taught by Shirley would be effective in the prevention and control of coccidiosis in poultry.

Applicant urges that they have submitted new claims and the rejection under Shirley is moot. Applicant urges that Shirley does not teach or suggest the subject matter of the newly submitted claims. Applicant urges the *Eimeria* strains of Shirley are distinct from that of the claimed *Eimeria* strains. Applicant urges that the organisms of Shirley provide immunity only after 41 days of challenge and Applicant urges that this is in contrast to the claimed *Eimeria* strains which realized a 21 day protective immune response. Applicant urges that the vaccine strains of Shirley have a 30% mortality rate which is in contrast to the claimed vaccines in which no treated bird suffered mortality.

Applicant's arguments filed October 8, 2003 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing of the record to show why the vaccine of the prior art teachings is not the same as the claimed invention. The claims are drawn to a vaccine comprising *Eimeria maxima, E. acervulina, E. tenella* and optionally at least one *E. necatrix.* Shirley teaches a vaccine composition which comprises live attenuated strains of *Eimeria* species in particular *E. necatrix* and *E. acervulina.* Shirley further teaches that the *Eimeria* species may be in the form of sporocysts and that other *Eimeria* species such as *E. maxima*, *E. brunetti, E. mivati, E. tenella* and *E. praecox* may be added to provide a fully effective coccidiosis vaccine. Applicant is urging limitations that are not in the claims with there assertion that "the vaccine strains of Shirley have a 30% mortality rate which is in contrast to the claimed vaccines in which no treated bird suffered mortality". There is no limitation or

requirement in the claims that suggest that the vaccine maintain a "particular rate of mortality". Applicant is urging limitations of intended use with their assertion that "that the organisms of Shirley provide immunity only after 41 days of challenge which is in contrast to the claimed *Eimeria* strains which realized a 21 day protective immune response. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). It should also be remembered that the claims are drawn to a product, a vaccine. Shirley teaches a vaccine that comprises the same *Eimeria* species as the claimed vaccine. Applicant has provided no side-by-side comparison to show that the claimed vaccine differs from the vaccine of the prior art. Therefore, the vaccine of the prior art anticipates or makes obvious the claimed invention.

5. The rejection under 35 U.S.C. 102/103 anticipated by or obvious over Schmatz et al is maintained for newly submitted claims 11-15 the reasons set forth on pages 9-10 paragraph 7 of the previous Office Action.

The rejection was on the grounds that Schmatz et al teach live sporulated oocysts that are administered to one day old chickens to provide immunity against coccidiosis without the need to provide supplemental anticoccidial therapy (see the Abstract). Schmatz et al teach that the vaccines of their invention include *E. necatix, E.*

acervulina, E, brunetti, E. mitis, E. mivati, E. praecox and *E. tenella* (page 2). Schmatz et al teach that the dosages of attenuated precocious oocysts range from about 5 to 1000 oocysts per bird for each *Eimeria* species included in the vaccine (page 3). Schmatz et al teach that the vaccines of their invention are preferably administered along with other material when the chicks are first processed. Process which administers other material to the chick, such as other vaccines. Schmatz et al teach that the aqueous oral suspensions of their invention include one or more suspending agents, thickeners or preservatives (claim 7, page 10).

Schmatz et al do not specifically teach one or more strains of *E. maxima* ARI-73/97, *E. acerculina* ARI-77/97, *E. tenella* ARI-11/98, E. necatrix MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said strains. However, in the alternative, the strains of Schmatz, et al appear to be obvious or analogous variants of the claimed vaccine strains. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the bacteria strains of Schmatz et al in a vaccine against coccidiosis because Schmatz et al teach vaccines that comprise live, attenuated, precocious strains of coccidial species, in particular *Eimeria.* It would have been expected, barring evidence to the contrary, that vaccines comprising multiple *Eimeria* species as taught by Schmatz et al would be effective in the prevention and control of coccidiosis in poultry.

Applicant urges that they have submitted new claims and the rejection under Schmatz et al is moot. Applicant urges that Schmatz et al do not teach or suggest the subject matter of the newly submitted claims. Applicant urges the *Eimeria* strains of Schmatz et al are distinct from that of the claimed *Eimeria* strains. Applicant urges that the organisms of Schmatz et al are distinct from the claimed vaccine for the same reasons as the organisms of MacDonald et and Shirley because the organisms of Schmatz et al are the organisms of MacDonald et and Shirley.

Applicant's arguments filed October 8, 2003 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing of the record to show why the vaccine of the prior art teachings is not the same as the claimed invention. The claims are drawn to a vaccine comprising *Eimeria maxima, E. acervulina, E. tenella* and optionally at least one *E. necatrix*. Schmatz et al teach that

the vaccines of their invention include *E. necatix, E. acervulina, E, brunetti, E. mitis, E. mivati, E. praecox and E. tenella (page 2).* Applicant is urging process limitations in a product claim with their assertions about sporulation times. It should be remembered that products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Applicant is urging limitations of intended use with their assertion about "number of days for protective immune response". It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Applicant is urging limitations that are not in the claims with there assertion about "rate of mortality". There is no limitation or requirement in the claims that suggest that the vaccine maintain a "particular rate of mortality". It should be remembered that the claims are drawn to a product, a vaccine. Schmatz et al teach a vaccine that comprises the same *Eimeria* species as the claimed vaccine. Applicant has provided no side-by-side comparison to show that the claimed vaccine differs from the vaccine of the prior art. Therefore, the vaccine of the prior art anticipates or makes obvious the claimed invention.

6. No claims allowed.

7. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
December 29, 2003

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